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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,978	06/24/2003	William Stillwell	1857-ARTI.0267US	2042

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,978	STILLWELL ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 2, 6, 9, 12, 15, 18 and 21 that recite the term ω-3 fatty acid, it is customary that the full name of the abbreviation be recited the first time the abbreviation is used in the claims. The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants need not confine themselves to the terminology used in the prior art, but are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained. During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969).

The remaining claims are indefinite to the extent that they read on the rejected base claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 12 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Katz et al. U.S. Patent No. 5,925,669.

Katz et al. teach pharmaceutical compositions comprising docosahexaenoic acid (DHA) and eicosahexaenoic acid (EPA) lipid conjugates with antineoplastic drugs such as chlorambucil, melphalan and methotrexate (column 7, lines 24-41) with oils such as phosphatidyl choline and phosphatidylethanolamines for the purpose of making liposomes (column 7, lines 56-61). The method for inhibiting tumor cell growth comprising a lipid conjugated to an omega fatty acid and a chemotherapeutic agent in a buffer is recited wherein DHA, either as a free fatty acid or as 1 stearoyl-2-docosahexaenoyl-sn-glycero-3 phosphocholine (lipid conjugate) is incorporated in tumor plasma membranes and makes them substantially more permeable (column 3, lines 7-14) and combined with chemotherapeutic agents (column 7, lines 24-41).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8, 10, 11 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. U.S. Patent No. 5,925,669.

Katz et al. teach that specific triacyl glycerols with EPA and DHA in the 2-(sn2) position of glycerol provides a readily absorbed source of long chain omega 3 PUFA for nutritional supplementation purposes (column 2, line 65 to column 3, line 1). Further, intestinal absorption and lymphatic transport of DHA depends on intramolecular tracyglycerol structure and specific triacylglycerols with DHA in the sn-2 position and medium-chain saturated acyl substituents in the sn-1 and sn-3 positions are of value in

delivering DHA and in ensuring adequate bioavailability following enteral administration (column 4, lines 52-60).

It does teach the specific formulations of DHA conjugated to phosphatidylcholine at the sn-1 position and methotrexate conjugated to phosphatidylcholine at the sn-2 position, DHA conjugated to phosphatidylcholine at the sn-2 position and methotrexate conjugated to phosphatidylcholine at the sn-1 position, DHA conjugated to phosphatidylcholine at the sn-1 position and chlorambucil conjugated to phosphatidylcholine at the sn-2 position, DHA conjugated to phosphatidylcholine at the sn-2 position and chlorambucil conjugated to phosphatidylcholine at the sn-1 position, DHA conjugated to phosphatidylcholine at the sn-1 position and melphalan conjugated to phosphatidylcholine at the sn-2 position, DHA conjugated to phosphatidylcholine at the sn-2 position and melphalan conjugated to phosphatidylcholine at the sn-1 position, EPA conjugated to phosphatidylcholine at the sn-1 position and methotrexate conjugated to phosphatidylcholine at the sn-2 position, EPA conjugated to phosphatidylcholine at the sn-2 position and methotrexate conjugated to phosphatidylcholine at the sn-1 position, EPA conjugated to phosphatidylcholine at the sn-2 position and chlorambucil conjugated to phosphatidylcholine at the sn-1 position, EPA conjugated to phosphatidylcholine at the sn-1 position and chlorambucil conjugated to phosphatidylcholine at the sn-2 position, EPA conjugated to phosphatidylcholine at the sn-2 position and melphalan conjugated to phosphatidylcholine at the sn-1 position or EPA conjugated to phosphatidylcholine at the sn-1 position and melphalan conjugated to phosphatidylcholine at the sn-2 position,

however, It would have been made obvious to one of ordinary skill in art at the time it was made to employ the compositions as recited above motivated by the teaching of Katz et al. who teaches that intestinal absorption and lymphatic transport of DHA depends on intramolecular tracyglycerol structure and specific triacylglycerols with DHA in the sn-2 position and medium-chain saturated acyl substituents in the sn-1 and sn-3 positions are of value in delivering DHA and in ensuring adequate bioavailability following enteral administration (column 4, lines 52-60).

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

June 25, 2006

Ardin H. Marschel 6/26/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER